REMARKS

Claims 1-12 and 26-41 are pending in this application.

Claim 1 is amended above to overcome the examiner's claim objection and section 112 rejections.

No new matter is added to the application by way of the claim 1 amendments.

I. THE CLAIM 1 OBJECTION

The examiner objected to certain language used in claim 1.

The examiner's objection is overcome by amending claim 1 as suggested by the examiner.

II. THE SECTION 112, 2nd PARAGRAPH REJECTIONS OF CLAIM 1

The examiner rejected claim 1 under the 2nd paragraph of section 112 for being indefinite for several reasons.

The Applicant's amendments to claim 1 above are believed to overcome the examiner's rejections. In particular, claim 1 has been amended to incorporate the subject-matter of claim 8, i.e. a reporter gene construct comprising a DNA coding for an operative hormone responsive element linked to a promoter and a reporter gene. The amendment is considered to obviate the for clarity reasons objected claim language.

Further, based on the description (page 2, line 26 to 30 of the International publication), it is clear that the present hormone responsive element is activated, after ligand binding, by steroid and thyroid hormone receptors entering the nucleus. Finally, in accordance with the above passage and based upon the International publication, claim 1 is amended to define the steroid and thyroid hormone receptors as selected from estrogen receptor, androgen receptor, progestin receptor, glucocorticoid receptor and mineralocorticoid receptor.

III. TRAVERSE OF THE OBVIOUSNESS REJECTION

The examiner rejected claims 1, 7-12 and 26-41 for being obvious over Evans (USP 5,298,429) and the Quaedackers Article in view of Stuelpnagel (US2005/158702), Walt (US 6,210,910) and the Wilson Article.

A. The Examiner's Rejection

It is the examiner's position that Evans teaches a bioassay for identifying ligands for steroid hormone receptors using recombinant cell lines. It is the examiner's further position that Evans does not teach specifically using U2-OS cell lines for bioassays of steroid ligands or ligand modifiers. The examiner relies upon Quaedackers for teaching the use of U2-OS cell line for expressing hormone receptors and reported gene assays for detecting the steroid ligands in samples. The examiner notes that neither Evans nor Quaedackers teach making biosensor cell arrays for detecting steroid ligands in a sample. The examiner goes on to rely upon Stuelpnagel for teaching a biosensor array for one or more cells or cell lines which relies upon the fact that individual cells are biologically or chemically stimulated by the ligands in the cell environment and respond by producing a change in the cell or cellular environment. The examiner relies upon Walt and Wilson for similar teachings. The examiner concludes that it would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the generic cell lines taught by Evans with U2-OS cells taught by Quaedackers and to further array the recombinant U2-OS cells in a biosensor to detect steroid ligands and ligand modifiers as taught by Stuelpnagel, Walt or Wilson and generate live U2-OS cell base biosensor arrays. The examiner concludes that one of ordinary skill in the art would have been motivated to make and use U2-OS cell arrays with hormones and related compound detections because they are more sensitive and effective in detecting ligands in cellular environments. Moreover, the examiner claims that one of ordinary skill in the art would have reasonable expectation of success in using biosensors of U2-OS cellular arrays because the art teaches that it is routine to make recombinant cells with specific receptor and reporter for detecting ligands, toxic chemicals that effects cell pathways and specifically steroid hormones.

B. The Applicant's Traverse

1. Evans and Quaedackers teach away from their combination

All pending application claims are patentable at least because the examiner's obviousness rejection is illogical. In particular, the prior art expressly teaches away from combining Evans and Quaedackers as the examiner has. According to column 18, lines 49-54 of Evans, CV-1 based expression was selected because these cells lack any

endogenous steroid or thyroid hormone receptor. According to Quaedackers (page 1157, left column, last lines), U2-OS cell based expression was selected because lack of estrogen receptor expression. Considering these disparate teachings, the skilled person at the time of the invention would have not been motivated to replace the CV-1 cells of Evans – which do not express any hormone receptor - with the U2-OS cells of Quaedackers which are disclosed as not expressing the estrogen receptor. For at least this reason, the combination of Evans with Quaedackers is illogical and the examiner's obviousness rejection should be withdrawn.

2. The combination of Evans and Quaedackers does not result in the claimed invention

All pending claims are independently non-obvious and patentable because the combination of Evans and Quaedackers does not result in the claimed invention. According to Quaedackers (page 1164, right column), both ERalpha and ERbeta can bind a large number of ligands each inducing a different response. However, as can be seen in Table 2 of the present application, differential responses of ERalpha (first column) do not suffice to discriminate, for example, between progesterone, androstenedione, R1881 and dexamethasone. To discriminate between these compounds, the skilled person should have also realised that receptors other than ERalpha and ERbeta show binding of a large number of ligands each inducing a different response such as the androgen receptor (AR) and the progesterone receptor (PR).

Considering the above, Quaedackers does not disclose the limitation, expressed by Evans as necessary for steroid and thyroid hormone receptor expression, of a cell line lacking any endogenous steroid or thyroid hormone receptor. Further, Quaedackers does not disclose binding of a large number of ligands each inducing a different response for any receptor other than ERalpha and beta. As shown in table 2 of the present application, the disclosure of binding of a large number of ligands each inducing a different response for the ERalpha receptor does not suffice to detect the presence of ligands according to the present invention.

3. The amended claims are not obvious

Claim 1 is amended above to include "an expression plasmid coding for a different steroid or thyroid hormone receptor selected from the group consisting of estrogen

receptor, androgen receptor, progestin receptor, glucocorticoid receptor and mineralocorticoid receptor". The cited prior art, and in particular Quaedackers, does not disclose or suggest expressing the different receptors identified in Evans in an U2-OS cell line. As a result, all pending claims are non-obvious and patentable for this reason as well.

In light of the all above arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of the pending claims. If the Examiner believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,

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